

Remarks

Reconsideration of the above-identified application is respectfully requested.

The present invention relates to a novel cosmetic composition containing water soluble β -(1,3) glucans, with naturally intact β -(1,6) linked side chains. The claims have been amended to recite the intact β -(1,6) linked side chains where the side chains comprise β -(1,3) linkages or 0-4 consecutive β -(1,6) linkages. Support for these amendments appear on page 2 of the specification. The examiner has withdrawn claims 17-28 as being directed to an invention that is independent or distinct from the invention originally claimed. The newly added claims 17-28 according to the examiner are directed toward two separate methods of using the recited compositions. Method claims 17 and 23 are merely extensions of the previously presented "USE" claim 10. Therefore, extension of the subject matter should be included in the prosecution of the composition claims 11-16. Applicants respectfully request that the examiner reconsider the withdrawal of claims 17-28.

Claims 12-16 have been rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out the claimed subject matter of the invention. The claims have been amended to clearly define the invention.

Claims 11-16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Zulli et al reference in view of the Weitkemper reference.

The Zulli et al reference discloses a method of treating skin by application of glucan ether derivatives. It has been previously argued by the applicants that the glucans of the current application are different from the glucans recited in the Zulli et al reference. The presently claimed β -(1,3) glucans are not carboxymethylated. Further, the presently claimed glucans have all their β -(1,6)-connected side chains intact. This disclosure is fairly represented in the specification, however, the claims have been amended to show this feature of the invention. Neither the Zulli et al reference nor the Weitkemper et al reference teach or suggest a synergistic combination of glucan or chitosan.

The examiner also objected to the data presented in the application as being insufficient evidence of synergy in the skin aging and skin roughness tests. In the Example, in Table 1, the examiner states the subjects were not matched at the start in order to have fair comparisons. Further, the examiner stated that even for the sake of completeness, if one were to accept the position shown in the table, it is noted that the results for comparative example V1 wherein no chitosan is present provide essentially the same results as examples 1 and 2 which are the compositions of the invention.

Applicants have had difficulties interpreting the examiner's statement, "...the subjects were not matched at the start.." on page four of the Office Action dated 29 October 2003. In the Office Action dated 17 March 2003, on page six, the examiner stated that "...all measurements are made relative to the skin condition as it existed at the outset of the treatment". The examiner continues, "...there is no indication that the skin condition of the subjects who received

chitosan alone was the same at the start of the treatment as that of the subjects who received chitosan and β -(1,3) glucan".

It is Applicants' interpretation that the examiner holds that all subjects must have about the same degree of wrinkles at the outset of the study to give the data credibility. However, such strict exclusion criteria, not even practiced in clinical trials, run into both practical and theoretical problems. Proper homogeneity ultimately implies genetically identical individuals living in the same environment. In such a case, a group of individuals would not be necessary – two individuals would be sufficient: one receiving the treatment and one control. These studies would be obviously useless in a real – world case as the observed effect could only be relevant to the tested genotype. The fact that different subjects respond differently to a type a treatment is not an argument for making a cohort more homogenous. Typically, the object of including a certain subgroup is to improve the observed effects of a treatment. In other words, positive results in trials with rigorous exclusion criteria are less convincing. Moreover, such studies may preclude the chances to evaluate other subgroups, which, unexpectedly respond better.

In the current instance, the fact that the degree of wrinkles was not matched at the outset of the treatment is the strength of the study. Picking a certain subgroup would most probably make the synergistic effects more pronounced. Also, the inclusion criteria (female, age 35-50, wrinkles) gave the Applicants the opportunity to evaluate the effects of the composition on the subgroups assumed commercially interesting.

Applicants also respectfully disagree with the examiners statement that no synergy is shown in the results. The subjects of the testing received the novel composition (Table 1, composition 1) showed a faster than expected response to treatment than those treated with β -glucan and chitosans alone (Table 1, compositions V1 and V2, respectively). Hence, the composition according to the invention shows a surprising synergistic effect at days 7 and 14 both in regard to skin aging and roughness. This effect could not have been predicted by a skilled worker in the art based on the prior art at the time of filing this application.

In view of the above comments and amendments to the claims, Applicants respectfully submit that the claims now define patentable subject matter over the prior art and meet the requirements of 35 United States Code. Therefore, an early notice of allowance of the above-identified application is respectfully requested.

Respectfully submitted,



Attorney for Applicants
W. Dennis Drehkoff
c/o Ladas & Parry
224 South Michigan Avenue
Chicago, Illinois 60604
(312) 427-1300
Reg. No. 27193